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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/039,956	10/23/2001	Melissa K. Carpenter	091/009C	1602

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EXAMINER

TON, THAIAN N

ART UNIT PAPER NUMBER

1632

DATE MAILED: 12/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

10/039,956

Applicant(s)

CARPENTER ET AL.

Examiner

Thaian N. Ton

Art Unit

1632

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 15 September 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____

Claim(s) objected to: _____

Claim(s) rejected: 16-69.Claim(s) withdrawn from consideration: 1.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
10. ☐ Other: _____

Joe W. [Signature]
AU 1632

Continuation of 5. does NOT place the application in condition for allowance because: Applicants' arguments and amendments to the claims are not persuasive for reasons of record advanced in the prior Office action. The prior rejection of claims 16, 37, 40, 42-50 and 52 for obviousness-type double patenting is maintained for reasons of record, as no terminal disclaimer or cancellation of the copending claims are of record. The rejection of claims 53-62 and newly added claims 63-67 under 112, 1st paragraph, for enablement is maintained for reasons of record. Applicants argue that the amendment obviates the prior rejection because the claims have been amended to state that the undifferentiated stem cells are cultured in the absence of feeder cells on an extracellular matrix in a medium conditioned by feeder cells, and suitable feeder cells for conditioning medium include fibroblasts, mesenchymal cells and hES-derived cells. See p. 10-11 of the Response. Further, the newly added claims 66-69 do not recite the conditions under which the hES cells are cultured, because the culturing of the cells is not actually part of the claimed procedure. See p. 11 of the Response.

This is not persuasive. The amendment to the claims is not commensurate to the enabled scope of the claims. In particular, the enabled scope of the claims is found to be the culturing undifferentiated pPS cells on an extracellular matrix and in the presence of a fibroblast-conditioned medium. See p. 5 of the prior Office action. Further, the prior Office action sets forth that the teachings of the art support that ES cells require fibroblasts, or unidentified factors isolated from fibroblasts, to maintain the cells in an undifferentiated state. The specification fails to provide sufficient teaching, guidance or any evidence pertinent to the breadth of the amended claims which recite "medium conditioned from feeder cells" and specific embodiments which recite that the cells used to condition the medium are mesenchymal cells (see newly added claim 64, for example). Furthermore, it is reiterated that Applicants have failed to provide any particular and specific guidance with regard to conditioned medium, other than fibroblast conditioned medium, that when used as described, would maintain the hES cells in an undifferentiated state. There is no guidance for cells, such as mesenchymal cells (as presently claimed), which would be used to condition medium to maintain undifferentiated hES cells. See pp. 8-9 of the prior Office action. Furthermore, with regard to newly added claims 66-69, it is maintained that the claims require specific steps to enable them. In particular the recitation of the culture conditions (on an extracellular matrix, and in a fibroblast-conditioned medium) are required to enable the claims, as stated in the prior Office action and above. The lack of such a recitation fails to enable the claims because the only enabled method of culturing the hES cells as presently claimed, in feeder-free conditions, is in the presence of an extracellular matrix and in fibroblast-conditioned medium.

The petition to change inventorship, under 37 CFR §1.48(b), filed 9/15/04, has been considered and approved.